

Notice of Allowability

Application No.

10/605,086

Examiner

Joseph W. Drodge

Applicant(s)

MAJEED ET AL.

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment filed on May 18, 2005.
2. ☒ The allowed claim(s) is/are 1-6 and 19, now renumbered claims 1-7.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 052605.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gautam Prakash on May 26, 2005.

The application has been amended as follows:

Claim 1 has been amended and rewritten as follows: --

Claim 1. (Currently amended) A method of solubilizing at least one natural or synthetic forskolin, isoforskolin, or 7-deacetylforskolin in water, the method comprising:

- 1) suspending forskolin, isoforskolin or 7-deacetylforskolin in water containing a complexing/solubilizing cyclodextrin agent [wherein the cyclodextrin agent is the sole complexing/solubilizing agent];
- 2) agitating at room temperature; and
- 3) filtering to obtain a clear aqueous solution containing 0.09% to 6% of forskolin, isoforskolin, or 7-deacetylforskolin. --

Claim 5 has been amended and rewritten as follows: --

Claim 5. (Currently amended) A method of solubilizing at least one natural or synthetic forskolin, isoforskolin, or 7-deacetylforskolin in water, the method comprising:

- 1) dissolving forskolin, isoforskolin or 7-deacetylforskolin in an organic solvent selected from ethanol, acetone, ethyl acetate[,] and methylene chloride;

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- 2) recrystallizing forskolin, isoforskolin or 7-deacetylforskolin from the organic solvent;
- 3) complexing the forskolin, isoforskolin or 7-deacetylforskolin in water containing a complexing/solubilizing cyclodextrin agent selected from the group consisting of α , β , γ -cyclodextrins or their derivatized products, randomly methylated β -cyclodextrin (RAMEBCD), 2-hydroxy-propyl- β -cyclodextrin (HPBCD), and hydroxypropyl γ -cyclodextrin (HPGCD)[, wherein the cyclodextrin agent is the sole complexing/solubilizing agent];
- 4) agitating at room temperature for 4 to 160 hours; and
- 5) filtering to obtain a clear aqueous solution containing 0.09% to 6% of forskolin, isoforskolin, or 7-deacetylforskolin. --.

Each of claims 8,9,15-18 and 20-23 have been cancelled.

Claim 19 has been amended and rewritten as follows: --

Claim 19. (Currently amended) A method of solubilizing at least one natural or synthetic forskolin, isoforskolin, or 7-deacetylforskolin in water, the method comprising:

- 1) suspending forskolin, isoforskolin or 7-deacetylforskolin in water containing randomly methylated β -cyclodextrin (RAMEBCD) ;
- 2) agitating at room temperature; and
- 3) filtering to obtain a clear aqueous solution containing 0.09% to 6% of forskolin, isoforskolin, or 7-deacetylforskolin. --.

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The following is an examiner's statement of reasons for allowance: Independent claims 1,5 and 19 are all now distinguished over all of the prior art of record in view of combination of steps comprising suspending or complexing forskolin in **water** containing a cyclodextrin agent, agitating at room temperature and filtering to obtain a **clear aqueous** solution containing a forskolin compound. On further review, the prior art of record, especially Saettone et al patent 6,346,273, Muller et al patent 6,407,079 and Shutske patent 5,070,209 are found to generally suggest suspending or complexing forskolin in organic liquids containing a surfactant type solubilizing agent, followed by agitation and filtering to obtain organic solutions, that may be yellow, then followed by solubilizing the filtered forskolin-containing solutions in water.

More particularly, Saettone is primarily drawn to disclosure of using polyvinylpyrrolidone (PVP) and/or polyethylene glycol-glyceryl triricinoleate (PEG-GTR) to solubilize drugs (column 5, line 66-column 8, line 27) and specifically to solubilizing forskolin with PVP and PEG-GTR (see the Table on column 8 and Examples 1 and 12).

Muller et al, although teaching solubilizing eye-drop type drugs into aqueous solutions with cyclodextrin (column 3, lines 50-67), concerns solubilizing a different collection of drug compounds than Saettone, having the known characteristic of having a chemical structure to fit into the cavities of the cyclodextrin molecule (column 3, lines 16-24).

Claims 15-18 and 20-23 are held to be restricted by original presentation, from the previously examined claims of the application.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

May 26, 2005


JOSEPH DRODGE
PRIMARY EXAMINER